



COOK INCORPORATED  
750 DANIELS WAY, P.O. BOX 489  
BLOOMINGTON, IN 47402-0489 U.S.A.  
PHONE: 812.339.2235 TOLL FREE 800.457.4500  
WWW.COOKMEDICAL.COM

Date: October 7, 2015

## URGENT: MEDICAL DEVICE RECALL EXTENSION

ATTENTION: Risk Management/Recall Administration

### Details on affected devices:

Torcon NB<sup>®</sup> Advantage Beacon<sup>®</sup> Tip Catheters: catalog prefixes HNBR4.0, HNBR4.1, and only HNBR5.0 w/RUC suffix

Royal Flush<sup>®</sup> Plus Beacon<sup>®</sup> Tip High-Flow Catheters: catalog prefix HNR4.0

Slip-Cath<sup>®</sup> Beacon<sup>®</sup> Tip Hydrophilic Catheters: catalog prefixes SCBR4.0, SCBR4.1, and only SCBR5.0 w/RUC suffix

Shuttle<sup>®</sup> Select Slip-Cath<sup>®</sup> Catheters; catalog prefix SCBR4.5

Lot numbers: *Please see attached list for the products/lots that were shipped to your account*

### Description of the problem:

Cook Medical is extending the voluntary recall of July 2, 2015, to include additional lots and catheter prefixes as listed above. These catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Cook Medical has received additional reports of catheter tip splits and/or separation. On the basis of these reports, Cook Medical is extending our voluntary recall to all lots that are in distribution.

Potential adverse events that may occur as a result of catheter tip splitting and or separation may include loss of device function, medical intervention to retrieve a separated segment, or complications resulting from a separated tip occluding blood flow to end organs.

Our records indicate that your facility has received devices that are subject to this recall.

### Action to be taken:

1. Please review the attached list of affected products and lot numbers that were shipped to your account, and quarantine any affected product that remains unused.
2. Immediately collect and return all unused affected products to Cook Medical as soon as possible for credit.
3. Please complete the attached Recall Response Form and return to Cook Medical either with the product or separately.
4. Please report any adverse event to Cook Medical Customer Relations at (800) 457-4500 or 1(812) 339-2235, Monday through Friday between 7:30 a.m. and 5:00 p.m. Eastern Daylight Time or by e-mail at [CustomerRelationsNA@cookmedical.com](mailto:CustomerRelationsNA@cookmedical.com).

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail), or
- Call the FDA at 1-800-FDA-1088

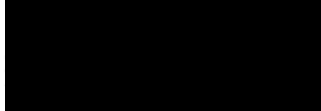
### Transmission of this notice:

This notice must be passed on to appropriate personnel, including down to the user level, within your organization or to any organization where the potentially affected devices have been transferred.

This recall is being made with the knowledge of the Food and Drug Administration.

We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter. Should you have any questions or concerns, please do not hesitate to contact Cook Medical Customer Relations at (800) 457-4500 or 1(812) 339-2235. We look forward to your response.

Cook Medical



B. Thomas Roberts  
Vice President, Quality Assurance